MODULAR CASSETTE SYNTHESIS UNIT

This application is a continuation application of U.S. patent application Ser. No. 13/550,026 filed on Jul. 16, 2012, titled "MODULAR CASSETTE SYNTHETSIS UNIT", which claims priority to U.S. Provisional Patent Application No. 61/508,373 filed on Jul. 15, 2011, titled "Modular Cassette Synthesis Unit"; U.S. Provisional Patent Application No. 61/508,294 filed on Jul. 15, 2011, titled "Systems, Methods, and Devices for Producing, Manufacturing, and Control of Radiopharmaceuticals-Full"; and U.S. Provisional Patent Application No. 61/508,359 filed on Jul. 15, 2011, titled "Cassette Reaction Vessel Using a Cascade of Valveless Pressure Pumps." Each of the above applications is incorporated by reference herein in its entirety.

BACKGROUND OF THE INVENTION

1. Field of Invention

Aspects of the present invention relate to methods and systems for reagent interaction in a modular context. More specifically, aspects of the present invention relate to methods and systems that effectuate and control reagent interaction through the remote action of pneumatic valves in a modular context.

2. Background

Nuclear medicine is a branch of medical imaging that uses small amounts of radioactive materials to diagnose or treat a variety of diseases, including many types of cancers, heart disease, and other abnormalities within the body. For example, positive emission tomography (PET) is a type of nuclear medicine imaging in which a radiopharmaceutical that includes a radionuclide tracer is introduced into the body where it eventually accumulates in an organ or area of the body being examined. The radionuclide gives off energy in the form of POSITRONS, which are detected by devices, including a PET scanner. In PET, radiopharmaceuticals that incorporate the radionuclide fluorine-18, such as fluorodeoxyglucose (FDG), 3'-deoxy-3'[^{18}F]-fluorothymidine (FLT), [^{18}F]-fluoromisonidazol (F-MISO), (4-[^{18}F]-fluorobenzoyl) norbiotinamide (FBB) and PET Perfusion Agents (PPA), are commonly used.

Due to the radioactive nature of radiopharmaceuticals, special consideration must be taken in their preparation, handling, and delivery. Production of fluorine-18 for use in a radiopharmaceutical is often difficult and/or expensive, requiring specialized equipment, such as a cyclotron. The production of the radioisotope often occurs at a remote facility by a third party, from which the hospital or lab receives patient doses that are ready to inject. Even if the radioisotope happens to be produced on site, final production of the radiopharmaceuticals used in many diagnostic imaging procedures requires manual preparation in a special aseptic environment to ensure a safe injectable product that is free of environmental contaminants. In addition, precise accounting of the radioactive nature of the radionuclide to be used in the radiopharmaceutical for each procedure is required, while taking into account that the bulk radionuclide product continuously decays over time.

Furthermore, during preparation of radiopharmaceuticals, technicians must be shielded from the ionizing radiation of the radionuclide, and the purity of the radiopharmaceutical must be ensured by filtering and/or avoiding contamination through contact with particles in the air, on a surface, and/or when mixing with a diluting liquid, for example. In addition, because of the short half-life of the radionuclide, the efficient scheduling of patients, for example, along with a safe and

efficient preparation of the radiopharmaceutical by technicians is critical to avoid wasting the prepared bulk product of the radionuclide.

Shielded containment systems for use in combining cyclotron-produced radionuclides with non-radionuclide components to produce radiopharmaceuticals have been developed. There are, however, many drawbacks of these systems. In particular, typically only one radiopharmaceutical may be produced in a production run. After a run, various radionuclide raw material components and physical system components must be replaced or decontaminated, which can greatly delay the production process and/or make the process much less efficient. Further, many aspects of production of radiopharmaceuticals in such related art systems are not automated and/or may require time-consuming and/or awkwardly controllable hand production steps. In addition, the radioactivity and/or quantities of the raw radionuclide and/or the produced radiopharmaceutical may be inaccurate and/or difficult to determine precisely. Necessary quality control to be performed on the output radiopharmaceutical products may be time-consuming, inaccurate, and/or require high levels of worker input/skill, further hampering production and/or timely delivery of the produced radiopharmaceuticals.

In addition, to carry out a process in which chemical reactions between a variety of reagents are to take place, such as in the production of radiopharmaceuticals, a large and complex setup is sometimes needed to channel liquids, reagents and/or compounds towards a reactor vessel. Channeling various ingredients towards the reactor vessel generally involves the use of tubing, threaded connectors, waiving and the like, which are often a source of fluid losses due to fluid being retained or trapped therein. The uncertainty and un-repeatability of such losses can create errors in determining the respective amounts of ingredients necessary to complete a desired reaction process with a desired specific yield. Moreover, some ingredients or reagents may have a short shelf life and may have to be used very quickly after manufacture or after exposure to the environment, which further increases the need for complex reaction vessels.

Accordingly, there is a need in the art for systems and methods that provide for chemical and/or physical interactions between a plurality of reagents and ingredients, while reducing or eliminating the need for excessive connections, tubing, and the like, particularly for the synthesis of chemical compounds such as, for example, radiopharmaceutical products, that are typically used in small quantities and that utilize reagents having a short shelf life. For example, the radioactive input may be a radioactive isotope typically produced in a cyclotron. There is a further need in the art for methods and systems that provide for chemical and/or physical interactions between a plurality of reagents and ingredients, while ensuring that subsequent reactions are not contaminated by remnants from previous reactions by providing, for example, one or more disposable reaction modules. There is a further need in the art for methods and systems in which one or more reaction modules may be removably connected to one another, as such methods and systems may be useful in providing the ability to quickly and efficiently dispose a plurality of ingredients and/or reagents in contact with each other in a reaction vessel or chamber. There is a further need in the art for systems and methods that provide for chemical and/or physical interactions between a plurality of reagents and ingredients when the reagents have a relatively short lifetime and must be mixed within a short period of time after being manufactured or exposed to the environment.